ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

March 11, 2008

The Honorable David M. Walker
Comptroller General
U.S. Government Accountability Office
441 G St., N.W.
Washington, D.C. 20548

Dear Mr. Walker:

Since last year the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce (Committee) has held hearings on the safety of our nation's drug supply. As part of that investigation, Minority Committee staff reviewed the Food and Drug Administration's (FDA) enforcement practices with respect to clinical investigators who have engaged in serious misconduct. That review revealed several troubling deficiencies in FDA's oversight and discipline of clinical investigators. For example, on October 23, 2003, Dr. Anne Kirkman-Campbell was convicted of Federal mail fraud relating to her participation in a clinical trial of the investigational drug Ketek. However, as of March 2008, Dr. Kirkman-Campbell had not yet been debarred pursuant to 21 U.S.C. § 335a(2). Moreover, Bloomberg News recently reported that FDA has failed to complete disciplinary action against 12 researchers, after proposing disqualification, and that cases have remained unresolved for as long as a decade.

The FDA's delay in initiating disciplinary proceedings is a critical one, as clinical investigators who have engaged in misconduct are still eligible to receive investigational drugs until the FDA disqualifies them.

We believe it is imperative that FDA's practices against clinical investigators engaged in serious misconduct be reviewed thoroughly and expeditiously, as the FDA's delay in bringing disciplinary action against these individuals places the participants in clinical trials and the integrity of the data gathered during the trial at significant risk. For this reason, we respectfully request that the Government Accountability Office examine the following issues:

(1) The reasons for delay with FDA initiating disciplinary proceedings against clinical investigators who have engaged in misconduct;

(2) Whether FDA Biomedical Research monitoring program is effective in identifying clinical investigators whose practices or conduct may compromise the quality and integrity of clinical data or the safety of participants in clinical trials; and, if not, what steps are being taken by FDA to address these issues.

Thank you for your prompt attention to this request. Please do not hesitate to contact Karen Christian, Minority Counsel, at (202) 225-3641 if you have any questions about this request.

Sincerely,

Joe Barton
Ranking Member
Committee on Energy and Commerce

John Shimkus
Ranking Member
Subcommittee on Oversight and Investigations

cc: The Honorable John D. Dingell, Chairman
Committee on Energy and Commerce

The Honorable Bart Stupak, Chairman
Subcommittee on Oversight and Investigations